DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 20, 2015

McGinley Orthopaedic Innovations
% Mr. Justin Eggleton
MCRA, LLC
1311 H Street North West, 12th Floor
Washington, District of Columbia 20005

Re: K143191
Trade/Device Name: McGinley Innovations IntelliSense Drill
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: Class I
Product Code: HWE, GEY, GFG, HTW
Dated: January 30, 2015
Received: February 3, 2015

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143191

Device Name
McGinley Innovations IntelliSense Drill

Indications for Use *(Describe)*
The IntelliSense Drill is intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc. In Bicortical mode, the IntelliSense Drill is indicated to be used in bicortical long bone, such as the femur, tibia, fibula, humerus, ulna, and radius.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary

DATE OF PREPARATION:	November 5, 2014
COMPANY/OWNER:	Dr. Joseph McGinley McGinley Orthopaedic Innovations 2435 King Blvd, Ste 230 Casper, WY 82604
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DEVICE TRADE NAME:	IntelliSense Drill
COMMON NAME:	Surgical Drill and accessories
CLASSIFICATION NAME:	Surgical instrument motors and accessories/attachments
REGULATION NUMBER:	21 CFR §878.4820
PRODUCT CODE:	HWE
SUBSEQUENT PRODUCT CODE:	GEY, GFG, HTW
DEVICE CLASS:	Class I
PREDICATE DEVICES:	Stryker Total Performance (TPS) System, K943589
DEVICE DESCRIPTION:	The IntelliSense Drill device will contain a drill unit (with attached cable), Control Console, and Sterilization Tray. Proprietary Drill Bits and Drill Bit Bushing will be sold separately as accessories. The drill bits and companion bushings are sold as a pair and are disposable (single-procedure). The IntelliSense Drill's design combines the drilling and depth measurement processes into one procedure, which determines drill bit location. By monitoring the load placed upon the drilling mechanism, the precise location of the drill bit may be determined relative to the bone. Secondary depth monitoring will provide the measurement of the drill bit depth and appropriate screw size.
INTENDED USE:	The IntelliSense Drill is intended to bore a hole into bone for

insertion of a screw, wire, cable, plate, pin, bolt, etc. In Bicortical mode, the IntelliSense Drill is indicated to be used in bicortical long bone, such as the femur, tibia, fibula, humerus, ulna, and radius.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The IntelliSense Drill demonstrates substantial equivalence to the Stryker Total Performance (TPS) System, K943589. Table 5-1 summarizes the key technological characteristics and features of both the predicates and the new device.

Table 5-1: Comparison of Proposed Device with Predicate Devices

Feature	IntelliSense Drill	Predicate
		Stryker Total Performance System
510(k) Number		K943589
Intended Use	The IntelliSense Drill is intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc. In Bicortical mode, the IntelliSense Drill is indicated to be used in bicortical long bone, such as the femur, tibia, fibula, humerus, ulna, and radius.	The Stryker Total Performance (TPS) System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, teeth and other bone related tissue in a variety of surgical procedures, including but not limited to Dental, ENT, Neuro, and Endoscopic. It is also usable in the placement of cutting of screws, wires, pins, and other fixation devices. It can also be used to cut metal
Outer profile: Console	Control Console has a 7 inch diagonal graphical touch screen for the user interface.	Bench-top style console with touch screen display and optional irrigation pump.
Operating Parameters:	User adjusts operating parameters via touch screen	User adjusts operating parameters via touch screen
System Status Display	Displayed on Touch Screen interface	Displayed on Touch Screen interface
Software	Microprocessor	Microprocessor
Non-volatile memory	System setup parameters such as touch screen calibration data, cortex breakthrough detection parameters and drill bit offsets. The setup parameters can be viewed, updated, and set to their default values, using the internal USB port on the SBC.	All current setting are stored when the power is down.
Energy (input)/Power Source	AC	AC
Console Controller Operation:	commercial bidirectional motor controller	Bidirectional
Weight	1.5 Kg (3.3 lbs)	1.36 Kg (3.0 lbs) [TPS Universal Driver]
Dimensions: Drill	Drill to fit in envelope of size 295mm x 195mm x 40mm	Not stated

Feature	IntelliSense Drill	Predicate Stryker Total Performance System
Materials: Drill	Stainless Steel AISI 316	Stainless Steel
Accessories		
Materials: Sterilization Tray	5052-H32 Aluminum, Silicone, 302 Stainless Steel, 304 Stainless Steel Radel, 430 Stainless Steel	N/A
Materials: Drill Bit	Stainless Steel: AISI 17-4	N/A
Materials: Drill Arm Bushing	Polycarbonate	N/A
Technological Characteristics		
Design:	The IntelliSense Drill is comprised of three primary subsystems: the Drill Unit (with attached cable), the Control Console, and the proprietary Drill Bits.	The device description of the Stryker System includes drills, shavers, shields, guards, motors, attachments, saws, wire drivers, collets, console, irrigation pump, cords, footswitch, handswitch, clips, tubing, cutting accessories, and sterilization cases.
Bidirectional Motor	Forward / Reverse Trigger	Forward / Reverse Trigger
Drill RPM	speeds up to 1,200 rpm	1,500 rpm [TPS Universal Driver]
Torque	Peak torque 1.9Nm with 0.3 Nm continuous torque at speeds up to 1,200 RPM	3.3 Nm [Stryker System 2000]
Drill Bit Depth Measurement	By monitoring the load placed upon the drilling mechanism, the precise location of the drill bit may be determined relative to the bone. Secondary depth monitoring will provide the measurement of the drill bit depth and appropriate screw size.	Manual depth gauge to determine proper screw size

Conclusions:
McGinley Innovations provided sufficient information to demonstrate the IntelliSense Drill is substantially equivalent to predicate Stryker Total Performance System (K943589).